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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,222	12/18/2001	Tsutomu Kakuyama	Q67737	7906

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EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,222

Applicant(s)

KAKUYAMA, TSUTOMU

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15, 17, 19, 21, 23 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) 27-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 17, 19, 21, 23 and 25-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 13-15, 17, 19, 21, 23 and 25-38 are pending in the application.

Election/Restrictions

Applicant's election of Group I, claims 13-15, 17, 19, 21, 23 and 25-26 in the response filed 4/19/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 27-38 are hereby withdrawn from further consideration on the merits as they are directed toward a non-elected invention.

Claims 13-15, 17, 19, 21, 23 and 25-26 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 102/103

Claims 13-15, 17, 19 and 21 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Light et al. (US 5,895,810).

Applicant's arguments pertaining to this rejection were fully considered, but not found convincing.

Applicant's principal argument resides in the contention that Light et al. did not teach an 'agent for clinical laboratory test' and also did not teach a chelating agent.

It is noted that the language 'agent for clinical laboratory test' is merely intended use language that does not materially change the composition: Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

It is further pointed out that Light et al. did disclose the formulation in a chelating agent for hemoglobin assays (see for example, p.21, lines 37-49).

Claim Rejections - 35 USC § 103

Claims 23 remains rejected and claims 25-26 (added in the response of 1/4/04) are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Light et al. (US 5,895,810) in light of Fiechtner et al. (US 5,686,316)* and in light of Stark (US 6,124,134)*. Claim is drawn to wherein the hemoglobin is glycated hemoglobin.

Applicant's arguments were fully considered, but not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants argue that Fiechtner et al. do not teach an 'agent for a clinical laboratory test', a hemoglobin compound or a chelating agent (p.9-Arguments).

Applicants further contend that:

'stabilization of the hemoglobin is not a sufficient required condition for use as an agent. The influence of a false positive reaction due to a contaminant in the measurement should be considered. It is disclosed that cysteine, etc., are effective for stabilizing Hb, when it is used as a blood substitute. However, a chelating agent or saccharide is also required together as indispensable ingredient when it is used as the agent for the clinical test. Without addition of such additives, accurate measurement of the Hb can not be obtained" (pp. 9-10 Arguments).

However, as it was deemed in the previous Office Action, the teachings of Fiechtner et al. and Light et al. obviate the claimed invention. It is clear that Light et al. added a chelating agent to the hemoglobin preparation for analysis. What was further clear is that some of the hemoglobin disclosed by Light et al. would have been glycosylated as evidenced by Fiechtner et al.

Applicants further argue that 'The descriptions of Stark and Fiechtner et al. relate to a relation between glycohemoglobin and hemoglobin in blood. Regardless of the description of G-Hb's agent in the Fiechtner et al. reference, how to stabilize Hb is not disclosed at all" (p.10 – Arguments). However, it is again noted that Fiechtner et al. and Stark were merely cited in order to relay an inherent and/or intrinsic property of hemoglobin and were not used as the basis for rejection. Light et al. *alone* performed the method or made obvious the method as Instantly claimed as evidenced by Fiechtner et al. and Stark et al.

*These references are cited in order to relay inherent and/or intrinsic properties and are not used as the basis for rejection *per se*.

No Claims are allowed.

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

06/14/04

A handwritten signature in black ink, appearing to read 'Patricia Leith', written in a cursive style.

**PATRICIA LEITH
PRIMARY EXAMINER**